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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/253,973	06/03/94	MCBRIDE W	DITI109

HM42/0724

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ART UNIT	PAPER NUMBER
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1616

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DATE MAILED: 7/24/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 6-9-98

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 2-8 and 10 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 2-8 and 10 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d):
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☒ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No.(s): 25 (1 sheet)
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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Response to Amendment

The amendment filed 6-9-98 has been entered. Claims 1, 26-29, 31 and 37 have been canceled. Claims 2 and 5 have been amended.

Response to Arguments

The Applicant's response in the amendment filed on 6-9-98 has overcome all of the grounds of rejection set forth in the office action mailed 2-5-98. Therefore, said rejection(s) are hereby withdrawn.

Applicant's arguments with respect to claims 2-8 and 10 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris (USP 5,688,485) in view of Fritzberg (USP 5,091,514), for the reasons set forth in the following new grounds of rejection.

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The instant claims appear to be directed to metal chelators having a targeting agent linker thereto having the formula as shown in claim 2. The ligands appear to have a donor atom set of NNNS.

Harris discloses ligands having the formula as shown in column 3, wherein Z is an amino group of the formula, $R_{17}-N-R_{18}$, yields ligands having the donor set SNNN or NNNS (stereoisomeric forms, see column 4, lines 40-45). The formula substituted wherein, R_6 together with R_7 and R_{13} together with R_{14} , to form an oxygen atom (see column 3, lines 57 and 60) and the remaining R_1-R_{18} groups are substituted with H, alkyl moieties, etc., would yield compounds within the scope of the ligands of the instant claims, except for such compounds would not include a linker and targeting moiety, as instantly claimed. The ligands form complexes with various radiometals, such as Tc-99m, etc. for use as radioimaging agents, see column 4, lines 1-14.

Fritzberg discloses ligands which may have the donor set SNNN which are used as radiopharmaceuticals for methods of diagnosis or therapy. Fritzberg teaches that such ligands may be conjugated to a targeting compound to provide the advantage of being able to specifically deliver the ligands to a target site *in vivo* for methods of diagnosis or therapy, see columns 6-7. The targeting agents may be conjugated to various substituents of the ligands and may include a linking moiety to facilitate the conjugation of the targeting moiety, see column 7, lines 41+. The linker may form an amide linkage with a polypeptide (e.g., as encompassed by the instant claims), see column 8.

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Since Harris and Fritzberg both disclose ligands and radiometal complexes thereof having the same utility as radioimaging and/or radiotherapeutic agents, they may be viewed as being in the same field of endeavor.

Although Harris may not disclose that the ligands may be conjugated to a targeting agent or that such conjugation may be through a linker, it would have been obvious to one of ordinary skill in the art to conjugate a targeting agent to the ligands disclosed by Harris using a linker (e.g., amide, etc.) because it is well known in the art that ligands may be conjugated to various targeting via various linking moieties, such as amide linkage to a peptide, to improve the biodistribution of the ligand for use as an imaging agent, as shown by Fritzberg.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for the instant claims of this application. Said application, 07/807,062, now Pat. 5,443,815 does not disclose or teach compounds having the formula of the instantly claimed reagents. Thus, the effective filing date for the instant claims is the date of filing of the instant application, 6/4/94.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Michael Hartley whose telephone number is (703) 308-4411. The

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examiner can normally be reached on Tuesdays through Fridays and on alternate Mondays from 7:30 a.m. to 5:00 p.m.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

M. Hartley



Date: 7-22-98



JOSE G. DEES
SUPERVISORY PATENT EXAMINER
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